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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,277	03/01/1999	KENJI KAWADA	32-248P	8984

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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/214,277	KAWADA ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,35,37,40,42-49 and 52-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34, 35, 37, 40, 42-49 and 52-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, which included addition of new 74-83 and amendment to claims 42,44, 52-54, filed on 1/28/2005, is made of record. Claims 34, 35, 37, 40, 42-49 and 52-83 are now pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 35, 37, 40, 42-49 and 52-83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making pharmaceutically acceptable salts does not reasonably provide enablement for making hydrate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record. To repeat: The following apply.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The factors to be considered in making an enablement rejection have been summarized above. In the present case the important factors leading to a conclusion of

undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

There is no working example of any hydrate formed. The claims are drawn to hydrate, yet the numerous examples, which show process of making nearly 2500 compounds, presented in specification pages 49- 452, all failed to produce a hydrate. Thus a hydrate cannot be simply willed into existence by dissolving a compound in water or solvent containing water as evident from the numerous examples. As was stated in Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there, is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ...' no evidence that such compounds even exist." The same circumstance appears to be true here. Instant compound claims embrace hundreds of thousands of compounds and specification exemplifies nearly 2500 compounds, none of which is shown to form a hydrate. Although use of water and organic solvents a re taught in the process of making, it does not result in a hydrate or a solvate. Thus a solvate or hydrate cannot be willed into existence by use water and or solvents and specification clearly lacks in teaching or suggestion how to form a hydrate despite the lack of hydrate formation with the exemplified compounds. Although one trained in the art would know how to form a salt based on the structural-makeup of the compounds particularly due to at least presence of phenolic hydroxyl, there is no such feature known to suggest that these compounds would form a hydrate. There is no evidence

that hydrates of these compounds actually exists; if they did, they would have formed. Hence, applicants must show that hydrates can be made, or limit the claims accordingly.

g) The state of the art is that is not predictable whether solvates will form. As noted above, there are no known criteria that would suggest what compounds form hydrate. In the realm of physical chemistry, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is the compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. In the instant case of hydrate a similar reasoning apply. Although there are several structurally related compounds disclosed in the prior art of record including those cited in the Information Disclosure Statements, none of these compounds are shown to form hydrate. Thus, one trained in the art cannot get any guidance as to how to form hydrate with the instant compounds.

h) The breadth of the claims includes all of the hundreds of thousands of compounds of formula. (I). For examples, with 10 R groups each having at least 26 choices, three X choices and at least 11 Y choices, the instant compounds would be 26 X 26 X 26 X 26 X 26 X 26 X 26 X 26 X 26 X 26 X 3 X 11 = 4658514156561408 compound! Again this is a conservative estimate as optional substituents are excluded. Thus, the scope of

instant compounds claims is extremely broad. One trained in the art therefore do extensive and undue experimentation to see whether instant compounds would form a hydrate and if so which of these compounds would do so. This clearly calls for undue experimentation.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of solvate formation in general and hydrate formation in particular, and the lack of working examples regarding the hydrate of the claimed compounds embraced in the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to make the instantly claimed invention commensurate in scope with the claims.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to make Applicants' invention.

This rejection is same as made in the previous office action. Applicants' argument to overcome this rejection is not persuasive. The following apply to applicants' traversal.

First of all, applicants' assertion that examiner had not met the burden of prima facie case is incorrect and lacks factual basis.

1. Specication has no working example of hydrate of compound of formula (I) even though nearly 2500 compounds out of the genus of over 4658514156561408 compounds embraced in the claim 1, were made and all these 2500 were in contact with water. This is a fact. Thus specification has no enabling disclosure.

2. Examiner therefore searched the pertinent art in the related terphenyl area and could not find any support for such hydrates. Then examiner extended the search to the more general area of solvates and found West cited above. Examiner had clearly discussed the reason for applying West and had pointed out lack of predictability of the art in the solvate area. In addition, examiner had also pointed out this is applicable to hydrates as well. Examiner had considered water as solvent. The scientific basis is clearly evident.

Based on these two facts, examiner had made the scope of enablement rejection using relevant Wands factor. Contrary to applicants' argument, examiner had provided the scientific basis and a pertinent reference to support the rejection.

Hence, examiner had clearly met the burden of establishing the prime facie case. Applicants' assertion is therefore incorrect.

As for applicants' citation of In re Marzocchi and Horton, it should be noted that this case law relates to objective enablement. In the instant case, the objective enablement of hydrate is totally lacking as evident from the 2500 compounds made and hence the genus of 4658514156561408 cannot be deemed as objectively enabled.

As for rest of the traversal, the following apply.

Again, applicants' analysis of West lacks understanding the process of forming hydrate. Applicants are under the impression bring a compound in contact with water would always lead to hydrate. This is not the case and that is what West says. In addition applicants are not addressing the issue at hand. The issue is hydrate of instant compound not of copper sulfate or sodium sulfate or any other compound. If forming hydrate of any compound is deemed to be treated as objective enablement, applicants should show or provide a pertinent reference, which attest this universal fact. The main point of contention of applicants appears to be there is no undue experimentation and it can be done experimentally. But there is no evidence provided or available to show such a hydrate exists. Examiner had provided West as evidence, which shows unpredictability of solvate formation. In this context, it would be of undue experimentation as it is unduly extensive given the large genus of over 4658514156561408 compounds. One trained in the art had not only make these large genus but also has to find out whether such a compound would form hydrate. This really unduly extensive experimentation.

Applicants urge that compound I-1, I-226 and I-1140 and the like of present invention are dissolved in water or mixed solvent of water with a organic solvent, the substance precipitated from the solution **may form** a hydrate.

But specification, which provides details of experimental protocol, does not support this. These compounds were in contact with water and there is no indication that they formed

hydrate. Again applications' assertion is sepeculative or a prediction for which the basis is not clear. Applicants should support this statement with a pertinent reference.

As for applicants' comments that the state of the art and the predictability in the art weighs in applicants' favor, again examiner had searched the art related to hydrate in particular and solvate in general and could not find support. Applicants are urged provide a supporting evidence.

Again, as for applicants' argument what is known the art needed not be disclosed, applicants' should provide a reference, which teaches the terphenyl compounds or its analogs form hydrates. The issue can then be easily resolved upon reviewing such a reference. Examiner's search did not result in such a showing in the literature. The fact hydrates for some compounds were known or enabled or patented is not the same as enablement for hydrate of instant compounds as noted above.

Applicants also appear to be confused with contacting instant compound with water as in the form of tablets, granules etc with hydrate. Contacting or dissolving in water is not the same as hydrate.

Hence this rejection is proper and is maintained.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 74, 75, 76 and 78-83 are duplicates of claims 34, 37, 40, 44, 46, 49, 55, 56 and 59. Applicant is advised that should claims 34, 37, 40, 44, 46, 49, 55, 56 and 59. be found allowable, claims 74, 75, 76 and 78-83 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 77 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42 When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 77 is a product by process claim. A product (compound0 is a product irrespective of how the compound is made. There is no structural difference between the compound of formula I embraced in claim 34 (or any other compound claims) and product produced by the process of claim 42. The claim 77 is not rendered patentably distinct by a process directed to its preparation even though the process may be patentable. Note "Determination of patentability in "product by process" claims is based on product itself, even though such claims are limited and defined by process, and thus product in such claim is unpatentable if it is same as, or obvious from, product of prior art, even if prior product was made by different process" In re Thorpe 227 USPQ 964.

Also note In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972), the court held that "The lack of physical description in a product by process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is

Mukund Shah whose telephone number is (571) 272-0674. If Applicants are unable to reach Mukund Shah within 24-hour period, they may contact James O. Wilson, Acting-SPE of art unit 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

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4/302005